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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------|---------------|----------------------|------------------------------|------------------|
| 10/574,827 | 03/27/2007 | Akira Hayasaka | 14875-158US1 C1-A0319-P_U | 1961 |
| 26161 | 7590 | 10/22/2009 | | |
| FISH & RICHARDSON PC | | | EXAMINER | |
| P.O. BOX 1022 | | | KAM, CHIH MIN | |
| MINNEAPOLIS, MN 55440-1022 | | | | |
| | | | ART UNIT | PAPER NUMBER |
| | | | | 1656 |
| | | | | |
| NOTIFICATION DATE | DELIVERY MODE | | | |
| 10/22/2009 | ELECTRONIC | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

| | | |
|------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/574,827 | Applicant(s) HAYASAKA ET AL. |
| | Examiner CHIH-MIN KAM | Art Unit 1656 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 June 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,2 and 4-15 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,4,6,8-12 and 14 is/are rejected.
 7) Claim(s) 2,5,7,13 and 15 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 06 April 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 0/14/2009

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Status of the Claims

1. Claims 1-2 and 4-15 are pending.

Applicants' amendment filed June 18, 2009 is acknowledged. Applicants' response has been fully considered. Claims 1 and 5-7 have been amended, and new claims 12-15 have been added. Therefore, claims 1-2 and 4-15 are examined.

Withdrawn Claim Rejections -- 35 USC § 112

2. The previous rejection of claims 1-2 and 4-11 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of applicants' amendment to the claims, and applicants' response at pages 4-5 in the amendment filed June 18, 2009.
3. The previous rejection of claims 1-2 and 4-11 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 5 in the amendment filed June 18, 2009.

New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 4, 6, 8-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith *et al.* (U.S. Patent 5,792,838; Reference AC on the IDS submitted on 11/09/2007).

Smith *et al.* teach a method for increasing the stability of an immunoglobulin (i.e., IgM, IgG and the like) by adding a copper-ion chelating agent such as EDTA or a citrate into an immunoglobulin formulation, where the immunoglobulin formulation can be any type of immunoglobulin formulation intended either for storage and distribution or ultimate use, which may contain 0.5 to 20 mg/ml of antibody (column 4, lines 9-54), and where the immunoglobulin solution containing antibody and citrate is prepared by dialysis at 4 °C against 50 mM citrate (pH 6.0; Example 8; claims 1, 4, 6, 8-12 and 14). Although Smith *et al.* do not specifically use IgM as an example, the reference does indicate the invention is applicable to the stabilization of immunoglobulins of all classes including IgM (column 3, lines 44-51). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to use the method of Smith *et al.* to stabilize IgM protein. One would be motivated to use such a preparation for stabilizing IgM because Smith *et al.* indicate that such methods are successful in stabilizing any antibody. Moreover, there is a reasonable expectation of success that the preparation of immunoglobulin by Smith *et al.* would be functional with IgM based on the high level of skill in the art. Therefore, the invention is *prima facie* obvious.

Claim Objections

5. Claims 2, 5, 7, 13 and 15 are objected to because the claims are dependent from a rejected claim.

Conclusions

6. Claims 1, 4, 6, 8-12 and 14 are rejected; and claims 2, 5, 7, 13 and 15 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chi-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8:00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK
October 20, 2009